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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,428	01/14/2005	Huy Khang Vu	100750-1P US	9952

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,428	VU ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 13, 16 and 22 to 28 are pending in the instant application. Claims 14, 15 and 17 to 21 have been canceled as requested by Applicant in the correspondence filed 11 May of 2006.

2) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in lines 4 and 8 on page 5. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p), which states that:

> "When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion."

Correction is required.

3) The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application

specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

4) The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 1, 2, 4, 5, 7 to 11, 13, 18 and 22 to 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass a binding assay that can employ a nucleic acid encoding a "CB1b receptor" protein having other than the entire amino acid sequence presented in SEQ ID NO:2 of the instant application. Claim 1 requires a nucleotide sequence that is at least 95% identical to any nucleotide sequence capable of encoding the amino acid sequence of SEQ ID NO:2. Because three contiguous nucleotides are required to encode a single amino acid, and changing a single nucleotide in a codon is sufficient to change the amino acid encoded thereby, these claims encompass an isolated nucleic acid molecule encoding a "CB1b receptor" having an amino acid sequence that deviates from the amino acid sequence presented in SEQ ID NO:2 of the instant application, the only functional "CB1b receptor" described therein, by as much as 15%. Claim 1, when analyzed in view of the text in the fifth paragraph on page 6 of the instant specification, encompasses an isolated nucleic acid encoding a non-naturally occurring protein whose amino acid sequence can deviate from SEQ ID NO:2 by as many as 65 out of 439 amino acid residues. However, the instant specification does not provide the guidance needed to practice the claimed process with a "CB1b receptor" polypeptide comprising anything less than the entire amino acid sequence presented in SEQ ID NO:2.

The only manner described in the instant specification of using the claimed nucleic acid, polypeptide and analytical method is in the identification of compounds that have potential medicinal use because of their ability to agonize or antagonize the human "CB1b receptor" protein described therein, as indicated by the text beginning in the first full paragraph on page 11 of the instant specification. The claimed invention is only useful in so far as the "CB1b receptor" protein employed in the claimed assay responds in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

As indicated by the last paragraph on page 1 of the specification, a CB1b receptor of the instant invention is a member of the G protein-coupled receptor family. All of the members of this receptor family share a common structure consisting of an extracellular domain, three extracellular loops, an intracellular domain, three cytoplasmic loops and seven transmembrane domains. Because of this complex structure, one of ordinary

skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments having at least 85% or even 95% sequence identity to SEQ ID NO:2 are going to be functional, much less be capable of producing an authentic response that is predictive of that single, naturally occurring human receptor protein that is described in the specification. Because the instant specification does not identify those amino acid residues in SEQ ID NO:2 which are critical to the structural and functional integrity of a "CB1b" receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified "CB1b receptor" protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:2 and predict the effects of that change on the performance of that protein "by resort to known scientific law". Unless one can predict, with reasonable confidence, that an intentionally modified "CB1b receptor" protein is going to produce a response that is predictive of a native human "CB1b receptor" protein, the information obtained from that modified protein and a process that uses that modified protein is of no practical value.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 1 to 13, 16 and 22 to 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) Claims 1 to 13, 16 and 22 to 28 are vague and indefinite in so far as they employ the term "a CB1b receptor" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "CB1b receptor" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. The text in the fourth paragraph on page 4 of the instant specification states that CB1b is "a splice variant of the human CB1 receptor" "and has a deletion of exactly 99 nucleotides at the N-terminal from positions 64 to 162 compared to the sequence of wildtype human CB1 receptor". The text in the second paragraph on page 5 states that "[t]he invention also encompasses polynucleotides which encode the CB1b receptor of SEQ ID NO: 2, and variants thereof". Because the specification expressly identifies CB1b as a "variant" of CB1, then one of ordinary skill would conclude that CB1 would have to be a "variant" of CB1b and, therefore, encompassed by the instant invention. Given the conflicting definitions provided by the specification, that artisan would be incapable of determining if human CB1 is encompassed or excluded by the limitation "a CB1b receptor".

6.2) Claim 3 is vague, indefinite and confusing because the phrase "consisting of **a** nucleotide sequence of SEQ ID NO:1" implies that there is more than one nucleotide sequence in SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOHN ULM
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